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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/563,042	03/13/2006	Shubha Anand	BJS-620-406	8188

23117 7590 02/06/2009

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EXAMINER	
LOVE, TREVOR M	

ART UNIT	PAPER NUMBER
1611	

MAIL DATE	DELIVERY MODE
02/06/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/563,042	ANAND ET AL.	
	Examiner	Art Unit	
	TREVOR M. LOVE	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 August 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) *10-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *08/14/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgement is made of Applicant's response, amendment to the claims, and IDS all filed 08/14/2008.

Claims 1-32 are pending. Claims 10-32 are withdrawn as being drawn to non-elect species. Claims 1-9 are currently under consideration. As a point of clarification, claim 10 was withdrawn per Applicant's response (12/09/2007) to the species election (11/05/2007) wherein Applicant elected breast cancer.

Priority

Acknowledgement is made to Applicant's claim to priority of PCT/GB2003/02862.

Information Disclosure Statement

Acknowledgement is made to Applicant's IDS filed 08/14/2008, all references were considered. Furthermore, acknowledgement is made to the International Search Report listed on the IDS filed 01/03/2006, which has also been considered.

Specification Objections

Acknowledgement is made to Applicant's amendments to the abstract, specification, and title. In light of these amendments, the objections to the abstract, specification, and title are withdrawn.

The specification is objected because of the following informalities:

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1)

and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 and 1.825.

The instant application recites sequences that are not identified by SEQ ID No. (see at least page 21), and recites a nucleic acid sequence with more than 10 nucleotides or 4 amino acids, which is not identified by SEQ ID No. The Examiner also notes that the application contains no sequence listing either in the form of a paper copy or in a computer readable form. Appropriate correction is required.

Claim Objections

Acknowledgement is made to Applicant's amendment to claim 5, removing the extraneous "4" at the beginning of the second line. The claim objection, errantly identified in the previous Office Action as being drawn to claim 4, is withdrawn.

Claim Rejections - 35 USC § 112

The rejection of claims 1-9 as being rejected under *35 USC § 112, first paragraph, because the specification does not reasonably provide enablement has been withdrawn in view of Applicant's election of breast cancer.*

The rejection of claims 2 and 4 as being rejected under *35 USC § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of Applicant's amendment to the claims clearly identifying the scope of the derivative.*

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5 and 8-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hauf et al (Journal of Cell Biology) (IDS reference) as evidenced by Anand et al (Cancer Cell) (IDS reference).

Hauf discloses that hesperadin can be used to allow cells treated with paclitaxel to stabilize at a faster rate based on the interaction with the spindle assembly checkpoint (see page 288, column 1, last two paragraphs). The findings of Hauf indicate that hesperadin inhibits Aurora B and that Aurora B function is required for spindle assembly in human cells (see page 283, second column, last sentence). Said combination of paclitaxel and heperadin would have an effect on breast cancer cells. This is evidenced by Anand teaching that paclitaxel functions to treat breast cancer by causing the cells to proceed to apoptosis (see page 59, first column, last paragraph), and Anand also teaches that AURORA-A over-expression is present in breast cancer (see page 51, "significance") and functions to disrupt the spindle checkpoint that is activated by paclitaxel (see page 59, first column, last paragraph, through second column, first paragraph). This reads on **instant claims 1-5 and 8-9**.

Hauf fails to directly disclose delivery of said composition to an individual.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to administer the composition to an individual. One would have been motivated to do so since Hauf teaches the advantages of the composition on breast cancer cells, which effect individuals. Furthermore, Hauf identifies a nexus between hesperadin, Aurora B function, and spindle assembly in human cells (see page 283, second column, last sentence). There would be a reasonable expectation of

success in the combination since cell lines are normally tested prior to administration to an individual in order to determine their overall safety and efficiency.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hauf et al (Journal of Cell Biology) (IDS reference) as evidenced by Anand et al (Cancer Cell) (IDS reference) as set forth above for instant claims 1-5, in further view of Slamon et al (N.E.J.M.) as evidenced by Lange et al (EMBO Journal).

The teachings of Hauf as evidenced by Anand are set forth above wherein it is further noted that Hauf teaches that Aurora B antibodies have been utilized to overcome nocodazole-induced arrest in cultured cells which Hauf indicates suggests a direct role of Aurora B in the spindle assembly checkpoint (see page 292, first column, second paragraph, last sentence).

Hauf as evidenced by Anand fails to directly disclose that the Aurora kinase inhibitor is an antibody.

Slamon teaches a recombinant monoclonal antibody is utilized in breast cancer patients to aid in correcting the over expression of HER2 which is over-expressed in 25 to 30% of breast cancers (see Abstract, first eight lines). Lange shows that members of the Aurora Kinase family are over-expressed in tumor types, such as human colorectal, breast, prostate, and ovarian cancers (see page 5372, first column, last paragraph, fourth sentence).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize antibodies to mediate the over-expression of Aurora in a

breast cancer patient. One would have been motivated to do so since Slamon teaches the mediation of HER2 over-expression in breast cancer patients by the utilization of antibodies. There would be a reasonable expectation of success in the combination since Applicant identified in the instant specification that there are many well known methods of acquiring antibodies (see instant specification, page 7, lines 1-13). Furthermore, it was well known in the art that Aurora kinases are over-expressed in breast cancer patients, and it is also known in the art that antibodies can be used to mediate over-expression of HER2. One would have looked to various options to overcome the Aurora over-expression, such as antibodies. One would have particularly looked to antibodies since Slamon teaches a method of reducing HER2 gene over-expression by using antibodies (see Slamon (see page 783, last paragraph through 784, first paragraph).

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hauf et al (Journal of Cell Biology) (IDS reference) as evidenced by Anand et al (Cancer Cell) (IDS reference) as set forth above for instant claims 1-5, in further view of Obermiller et al (Breast Cancer Res) as evidenced by Lange et al (EMBO Journal).

The teachings of Hauf as evidenced by Anand are set forth above.

Hauf as evidenced by Anand fails to directly disclose that the Aurora kinase inhibitor is a sense or anti-sense nucleic acid.

Obermiller teaches that gene therapy is useful when trying to correct specific molecular defects that contribute to the cause or progression of cancer, specifically, breast cancer (see abstract).

It was well known in the art that Aurora kinases are over-expressed in breast cancer patients, and it is also known in the art that gene therapy can be used to can provide selective targeting of specific issues, such as Aurora kinase over-expression. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize sense or anti-sense nucleic acids to mediate the over-expression of Aurora in a breast cancer patient. One would have been motivated to do so since Obermiller teaches that gene therapy provides the ability to correct specific molecular defects that contribute to the cause or progression of cancer, this would include the over-expression of Aurora kinase in breast cancer patients. There would be a reasonable expectation of success in the combination since Applicant identified in the instant specification that there are many well known methods of down-regulating gene expression (see instant specification, page 8, lines 6-9 and page 10, lines 21-27).

Conclusion

No claims allowed. All claims rejected. No claims objected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TREVOR M. LOVE whose telephone number is (571)270-5259. The examiner can normally be reached on Monday-Thursday 7:30-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TL

/Lakshmi S Channavajjala/

Primary Examiner, Art Unit 1611

January 21, 2009